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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/619,142	07/19/2000	W. Ray Knowles	Knowles/HairLoss	1598

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EXAMINER
KIM, VICKIE Y

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 05/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Office Action Summary	Application No. 09/619,142	Applicant(s) KNOWLES, W. RAY	
	Examiner Vickie Kim	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-16 and 18-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-16 and 18-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3, 12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Gibson (US 5015470).

Gibson teaches a composition for topical application to hair for inducing, maintaining or increasing hair growth comprising minoxidil and penetration enhancer (see abstract and column 4, lines 40-42). It further teaches that the penetration enhancer potentiates the benefit of the chemical inhibitor by improving its the delivery through the stratum corneum to its site of action in the immediate environment of the hair follicle(see column 14, lines 5-10).

All the critical elements are taught by the reference. Thus, the claimed subject matter is not patentably distinct over the prior art of the record.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1-2, 12-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Crandall (US 6,333,057).

Crandall teaches a topical treatment for hair loss, especially alopecia, comprising administering a topical composition comprising 5α-reductase inhibitor(i.e. saw palmetto) and penetration enhancer(e.g. lecithin organogel); see claims 1-5, example 4, column 1, lines 52-53 and column 4, lines 26-43. It teaches that saw palmetto inhibits the action of the enzyme, 5 alpha-reductase which reduces the conversion of testosteone to dihydrotestosterone testosteone. It also teaches that the penetration enhancer increases the penetration of the active compound thru the skin; see column 4, lines 33-43. It further teaches that the site of action for hair growth is the hair follicle wherein the patented composition stimulates the activity of hair follicles and results in hair growth. One of skilled artisan would have envisaged the enhanced delivery of active compound to the site of action(i.e. hair follicle(bulb)) via improved penetration thru skin layers by penetration enhancer.

All the critical elements are taught by the cited reference. Thus, the claimed subject matter is not patentably distinct over the prior art of the record.

6. Claims 1-4 and 12-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Roentsch et al (US 5,654,337).

Roentsch et al teach topical application of a hair growth enhancer is achieved by incorporation of the patented delivery composition into the agent such as minoxidil or 5α-reductase inhibitor(e.g. finasteride). The topical hair growth composition comprises a therapeutically effective amount of minoxidil and penetration enhancer; or 5α-reductase inhibitor and penetration enhancer. Finally, it teaches that the incorporating a mixture of minoxidil and 5α-reductase inhibitor into patented formulation would be very beneficial for inducing increased hair growth due to very good skin penetration achieved using the patented formulation; see column 6, lines 5-20. It further teaches a topical composition for local delivery of a pharmaceutically active agent wherein penetration enhancer(i.e. speed-gel) is useful in the delivery of pharmaceutically active agents through the skin to provide local relief by local delivery to targeted active site of action(e.g. subdermal sites); see abstract , column 2, line 66 and column 4, lines 58-68. One of skilled artisan would have envisaged the enhanced delivery of active compound to the hair bulbs that is the targeted active site of action, in this case, via improved penetration thru skin layers by penetration enhancer(e.g.speed-gel).

Thus, all the claimed subject matter is not patentably distinct over the prior art of the record.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 5, 7-10, and 16, 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roentsch et al(US 5,654,337) in view of Crandall (US 6,333,057).

Roentsch et al's teaching is aforementioned in the 102 rejection (supra). Roentsch et al further teach that the minoxidil composition with penetration enhancer contains a concentration of minoxidil about 0.1% to 10%; see column 6, lines 9-10.

Applicants claims differ because claims 5 and 16 require the specific amount ratios between minoxidil and 5-α reductase inhibitor(i.e. 1gm:0.5gm). Claims 7 and 18 require specifically 0.5gms of 5α reductase inhibitor per 4 ounces of finished liquid.

Claims 8-10 and 19-20 require the label for specific topical use in maintaining condition or treating hair loss including alopecia.

Crandall's aforementioned teaching in the 102 rejection is about the topical composition comprising a therapeutically effective amount of combination of 5α-reductase inhibitor and penetration enhancer, and its improved local delivery and therapeutic efficacy. Crandall also teaches that his patented composition contains 0.25-20% of saw palmetto(5-α reductase inhibitor) that is equivalent to 0.3-20gm per 120ml solution; see claim 5. Each patentee teaches that the patented topical composition is

beneficially useful for hair growth, treating hair loss including alopecia and preserving healthier hair looks; see US'057, abstract and claims and US'337, column 6, lines 5-20. Thus, it would have been obvious to one having ordinary skill in the art to modify these teachings together to formulate the most effective topical composition having specific amount ratio as claimed because each patentee suggests the therapeutically effective amount of each active ingredients used in the treatment of the hair loss and for maintaining healthy hair using the same active ingredients and because the minor variations including the selection of optimal dosages or variable applications in order to determine the most effective treatment is well within the skilled level of artisan having ordinary skill in the art, and is obvious.

9. Claims 11 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roentsch et al(US 5,654,337) in view of Grollier et al(US 6,333,057).

As aforementioned immediately above, Roentsch et al teach a topical composition for enhanced delivery by improved penetration thru skin layer, comprising a minoxidil, 5α-reductase inhibitor and penetration enhancer(i.e. speed-gel).

Applicants claims differ because they require a sunscreen.

However, it would have been obvious to one of ordinary skill in the art to add the sunscreen to the Roentsch et al's hair growth composition when Roentsch is taken in view of Grollier et al because Grollier et al teach the addition of sunscreen into the topical hair growth formulation; see claims and examples.

One would have been motivated to add the sunscreens into the topical hair growth composition comprising minoxidil, 5α-reductatse inhibitor and penetration

enhancer, with reasonable expectation of success because the sunscreen protects the hair from damage of lackluster, discoloration or fading due to the sun, particularly U.V light. And also the sunscreen may retard and protect the scalp of alopecic subjects which is directly exposed to the possibly adverse effects of UV radiation in addition to , in the case of some of the sunscreen agents, improved solubilization of the minoxidil to be obtained as suggested in Grollier's reference. Most of all, one would have been motivated to do so because adding sunscreen into a hair growth composition because one would induce and stimulate hair growth and decrease hair loss when the sunscreen is beneficially added into a hair growth product containing monoxidil and other beneficial agents(e.g. 5α-reducatase inhibitor) in addition to that the superior quality of this combination composition of minoxidil and 5α-reductase inhibitor with improved penetration is achieved by incorporating a penetration enhancer; see column 2, lines 2-15.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same (or similar) ingredients and share common utilities, and pertinent to the problem which applicant is concerning. MPEP 2141.01(a).

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. All the pending claims are rejected. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is (703) 305-1675 (Tuesday-Friday: 8AM-6:30PM) or Marian Seidel (Supervisory primary patent examiner) at (703)308-4725.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

WILLIAM R. A. JARVIS
PRIMARY EXAMINER
ART UNIT 1614

Vickie Kim,
Patent examiner, Art unit 1614
April 24, 2002